DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

945621

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS
Our Reference: 3003621780

February 25, 2004

John Bos, Co-Owner
Arend J. Bos, Co-Owner
Maple Dairy
15857 Bear Mountain Blvd.
Bakersfield, California 93311-9413

WARNING LETTER

Dear Mssrs. Bos & Bos:

An investigation of your dairy operation in Bakersfield, California conducted by Food and Drug Administration (FDA) investigators on January 6 and 7, 2004 confirmed that you offered an animal for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. §§ 342(a)(2)(C)(ii) and 342(a)(4). You also caused an animal drug to become adulterated within the meaning of Section 501(a)(5) of the Act, 21 U.S.C. § 351, because the drug was used in a manner that does not conform with its approved use or the extralabel use regulations at Title 21, Code of Federal Regulations, Part 530 (21 C.F.R. § 530).

On or about September 9, 2003, you consigned a cow identified by United States Department of Agriculture (USDA) laboratory report number 435826 to be slaughtered for human food to [redacted] USDA analysis of tissue samples collected from that animal identified the presence of flunixin at 1.856 parts per million (ppm) in the liver. A tolerance of 0.125 ppm has been established for residues of flunixin in cattle liver (21 C.F.R. § 556.286). The presence of flunixin above established tolerance levels in the edible tissues from this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions whereby medicated animals bearing possibly harmful drug residues could enter the food supply. For example, our investigator observed the following:

1. Your firm fails to maintain an adequate system for assuring that drugs, specifically, [redacted] and [redacted] (Tetracycline Hydrochloride), are used in a manner consistent with their approved labeling or a written prescription from your veterinarian;

2. Your firm fails to maintain a complete, written medication treatment record system for your animals that includes all treatments, the amount of each drug administered, the route of administration, the drug pre-slaughter time, and the person who administered each drug; and

3. Your firm fails to maintain a drug inventory/accountability system.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for assuring that your overall operations and the food you distribute are in compliance with the law.

Our investigator also observed that you have adulterated the drug [redacted] that your firm uses on cattle within the meaning of Section 501(a)(5) of the Act when you failed to use the drug in conformance with its approved labeling or in accordance with a written prescription from your veterinarian.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not occur. Failure to do so may result in regulatory action, such as a seizure and/or injunction, without further notice.

You should notify this office in writing within 15 working days of receipt of this letter of the steps you have taken to bring your dairy into compliance with the law. Your response should include each step being taken, that has been taken, or that will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your response should be directed to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Kishida at (510) 337-6824.

Sincerely,

Charles M. Breen
Acting District Director
San Francisco District